

REMARKS

Claims 1-46 are presented for consideration by the Examiner. Some of the claims have been amended for purposes of improving the clarity of the claims, and every ground of rejection has been addressed.

Applicants note with appreciation the indication of allowable subject matter with regard to claims 3, 9, 12, and 18.

1. REJECTIONS OF CLAIMS UNDER 35 U.S.C. § 112 ARE TREATED

Claims 3, 7, 12, 27, and 37 were rejected under 35 U.S.C. § 112, first paragraph, for containing subject matter which was said to not be described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Regarding claims 3, 12, 27, and 37, support for the subject matter in which the support plate intersects with a surface in the proximal section of the stem means forming a smooth transition which is rounded, can be found at least on page 10, lines 5-11, and FIG. 1. Accordingly, Applicants respectfully submit that the subject matter of claims 3, 12, 27, and 37 is adequately supported in the specification and Applicants request that the rejection of these claims be withdrawn.

Regarding claim 7, support for the subject matter of claim 7 is disclosed on page 19, lines 23 to page 20 line 5, for example. Moreover, claim 7 has been amended herein to place the claim in a condition that is believed to overcome the rejection. Accordingly, Applicants respectfully request that the rejection of claim 7 be withdrawn.

Claims 4, 6, 7, 10 and 31 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Regarding claims 4, 7, 10 and 31, the rejections are believed to be overcome by amendments made herein which are consistent with said rejections.

Regarding claim 6, the Office Action indicated that it is not clear how the scope of claim 6 differs from claim 1. Applicants respectfully submit that the additional language in claim 6, including "to thereby enhance settling action of said flared plate surface against the load-bearing surface of the first bone" provides adequate subject matter to further limit claim 6 as compared to claim 1. Accordingly, Applicants respectfully request that the rejection of claim 6 be withdrawn.

Further regarding claim 10, the Office Action indicated that it is not clear what element encompasses the limitation of "a means for engaging with the second bone." Applicants respectfully submit

that the disclosure of the hip ball 38, as shown in FIG. 1, and disclosed on page 12, lines 20-24, is adequately described to be included as a means for engaging with the second bone member. Applicants note that the means for engaging with the second bone member is not positively recited in claim 10. Claim 10 only requires the second side to be configured to support the means for engaging with the second bone member. Accordingly, claim 10 is believed to be definite and Applicants request that the rejection of claim 10 be withdrawn.

2. REJECTIONS OF CLAIMS UNDER 35 U.S.C. §§ 102 AND 103 ARE TREATED

Claims 1, 2, 6-8, 10, 11, 15, 16, 19-26, 30, 31, and 44-46 were rejected under 35 U.S.C. §102(b) as being anticipated by Kirshner. Claims 4, 5, 13, 14, 17, 28, 29, 32-36, and 38-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kirshner in view of U.S. Patent No. 2,719,522 to Hudack.

Applicants' counsel has carefully studied the reasoning for the rejection provided in the Office Action, together with the prior art references relied upon. Applicants respectfully submit in good faith that certain aspects of the invention are unanticipated, nonobvious and allowable.

The primary reference relied upon in Office Action was the Kirshner, C-2 Osteocap Hip reference. The Kirshner reference is a

one page document, as shown in the enclosed copy of the document. The Office Action describes additional subject matter that is not part of the Kirshner reference, but which appears to have been accidentally commingled by the Office with the Kirshner reference. For example, a figure 11, and a surgical technique disclosed by Dr. Fenning are not disclosed in the Kirshner reference. The Office Action is apparently referring to a document entitled *Osteocaps, Hip System Surgical Technique*, (hereinafter the "Biomet reference") which was previously made of record in a prior related application, but which is not prior art with respect to any of the independent claims in the present application. The date indicated on the Biomet reference is 1997, whereas priority for the subject matter claimed in the present application dates back to 1994. Moreover, the Biomet reference does not disclose the feature of a spacial posterior gap and a spacial anterior gap, and is therefore not material to claims requiring that feature, including dependent claim 24. Accordingly, Applicants were not required and chose not to submit the Biomet reference in the Information Disclosure Statement and PTO form 1449 submitted on October 9, 2001. The apparent mistake on the part of the Patent Office to combine the Biomet reference with the Kirshner reference has tainted the Office Action such that Applicants respectfully request that the Patent Office make the next action non-final, if a notice of allowance is

not submitted. Applicants respectfully traverse the rejections made in the Office Action for at least the reasons explained below.

Regarding independent claims 1, 10 and 21, each of the claims requires a slot extending along the long axis. As shown in the copy of the Kirshner reference attached hereto, the Kirshner reference does not disclose a slot extending along the long axis. The slot referred to in the Office action is shown in the Biomet reference, which is not prior art for the present claims, for the reasons explained above. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegall Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since the Kirshner reference fails to disclose a slot extending along the long axis, Kirshner does not anticipate claims 1, 10, and 21. Moreover, the features of claims 1, 10, and 21 are not taught or suggested by Kirshner or the prior art of record. Accordingly, claims 1, 10, and 21 are believed to be allowable, for the reasons expressed above, and consistent with claims 3, 9, 12, and 18 which have already been indicated to be allowable in the Office Action.

Dependant claims 2-9, 11-20 and 22-24 depend from claims 1, 10, or 21, or a claim depending from those claims, and are therefore believed to be allowable for at least the reasons given in support of claims 1, 10, and 21.

Regarding claim 25, subject matter is required including a majority length of the stem means defining a common, non-varying radius. This subject matter is not disclosed, taught or suggested by Kirshner. Moreover, the other prior art of record does not disclose, teach or suggest all the subject matter of claim 25. Accordingly, claim 25 is believed to be allowable, for the reasons expressed above, and consistent with claims 3, 9, 12, and 18 which have already been indicated to be allowable in the Office Action.

Dependent claims 26-33 depend from claim 25 or a claim depending from claim 25 and are therefore believed to be allowable for at least the reasons given in support of claim 25.

Regarding claim 34, subject matter is required including wherein a distal-most portion of the proximal section is wider than a proximal-most portion of the distal section such that the distal-most portion of the proximal section and the proximal-most portion of the distal section cooperatively form a male corner therebetween. This subject matter is not disclosed, taught or suggested by Kirshner. Moreover, the other prior art of record, including the Hudack reference, does not disclose, teach or suggest all the subject matter of claim 34. Accordingly, claim 34 is believed to be allowable, for the reasons expressed above, and consistent with claims 3, 9, 12, and 18 which have already been indicated to be allowable in the Office Action.

Dependent claims 35-43 depend from claim 34 or a claim depending from claim 34 and are therefore believed to be allowable for at least the reasons given in support of claim 34.

Regarding claims 44-46, it is noted that the apparent mistake on the part of Patent Office has caused a commingling of the Kirshner reference with a non-prior art Biomet reference submitted previously in a parent application. The Office's rejection of claims 44-46 is based in part on figure 11 of the non prior art Biomet reference. Since the subject matter of claims 44-46 is entitled to a claim to the earliest priority date of July 14, 1994, and since the apparently-commingled Biomet reference identifies a date of publication of 1997, it is clear that the rejection of claims 44-46 is based on factual mistake and must therefore be withdrawn.

Further, claims 44-46 require the distinct subject matter of "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." Since the Office Action clearly relied on additional disclosure that is not part of the Kirshner reference in rejecting claims 44-46, Applicants reiterate the position explained in the preliminary amendment, that the Kirshner reference does not anticipate these claims. Anticipation requires a showing that "each element of the claim in issue is found, either expressly or under principles of inherency, in a single prior art

reference, or that the claimed invention was previously known or embodied in a single prior art device or practice." Minnesota Mining and Manufacturing v. Johnson & Johnson, 24 U.S.P.Q 2d 1321, 1326 (Fed. Cir. 1992).

It is unknown from a reading of the Kirshner drawing what exactly would be revealed by rotating the depicted stem ninety degrees to bring the medial lip under surface into view, in contrast to applicants' disclosure which includes the clear detail of FIG. 1A and corresponding written description. Such a view, or any disclosure corresponding to it, is unavailable in the mere side-view profile drawing of Kirshner, leaving any three dimensional environment of the medial lip undersurface unknown, and subject to speculation and hindsight analysis. Regardless of the two-dimensional, side-view profile of Kirshner, the actual medial-lip under surface exists in the context of a three-dimensional environment that may comprise one of any number of structural possibilities. Without some illustration or description in Kirshner to show the three dimensional environment, as in the manner of FIG. 1A of applicants' application, it would be speculation to presume whether the angle formed between the medial lip undersurface and the long axis of the stem would be greater than ninety degrees in the Kirshner prosthesis.

Claims 44-46 are therefore not anticipated because the Kirshner drawing does not expressly identify the subject matter "an

under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." The drawing would need to include something more, such as an angle symbol in reference to defined angle lines that are clearly greater than ninety degrees, or some other such specific teaching.

Furthermore, the Kirshner drawing does not expressly illustrate the multi-dimensional concept of the subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." The Kirshner drawing is a mere profile, and does not reveal the structure of the undersurface of a terminal portion of the lip. Ex parte Levy, 17 U.S.P.Q. 2d 1461, 1462 (Bd Pat App & Inter 1990), "Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference."

In addition to not expressly depicting or illustrating the element in question, Kirshner also does not inherently disclose the subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of

ordinary skill." In re Robertson, 49 U.S.P.Q.2d 1949, 1950 (Fed. Cir. 1999) (citations omitted) (italics added).

Because the Kirshner reference fails to show the undersurface of the terminal portion of the lip or discuss this feature in the written text, the angle of the under surface is not necessarily present in the Kirshner reference. It is possible that the Kirshner prosthesis could contain an indentation in the undersurface of the terminal portion of the lip such that the profile would appear as pictured in the Kirshner reference, but such that the angle of the undersurface with respect to the long axis would be less than 90 degrees. The requisite angle is therefore not necessarily present as required by the above authority for inherency, so the Kirshner drawing does not inherently disclose the invention. In re Robertson, 49 U.S.P.Q.2d 1949, 1950 (Fed. Cir. 1999) (citations omitted), "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

Regarding obviousness, the invention of claims 44-46 is also not obvious when Kirshner is combined with the other prior art references, since Kirshner provides no suggestion for an under surface of a terminal portion of a lip of the medial section to form an angle with the long axis of the stem means which is greater than ninety degrees. Kirshner not only fails to disclose the

subject matter in diagrams or written text, but is also silent as to the advantages of an undersurface of the terminal lip forming an angle with the long axis of greater than ninety degrees. The present invention allows incremental micro-motion that permits the prosthesis to gradually, ever so slightly, settle into a position of stability (see page 13, lines 4-16 of the specification).

The Federal Circuit has repeatedly cautioned against employing hindsight by using the applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teaching of the prior art. See, e.g., Grain Processing Corp. v. American-Maize Prods. Co., 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Applicants submit that this is a classic case where a reference must have some clear and specific suggestion or indication of the presence of the feature claimed, yet the Kirshner reference lacks such specificity. It is understandable that the Patent Office may initially choose to isolate certain elements in a patent and claim, with the benefit of hindsight, that the element or elements are present in the Kirshner drawing. However, in the absence of a specific suggestion, such a practice is tantamount to the Patent Office impermissibly using applicant's teachings to hunt through the prior art references for the claimed elements and concoct them in combination without suggestion. In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989). The Office must provide

specific, concrete documentation of the feature in the prior art, or some suggestion thereof. See Id.

The law cited above, and other similar authority, prohibit such hindsight speculation to be relied upon for a finding of unpatentability. Indeed, it would take a retrospective view of the Kirshner drawing, in light of applicants' discovery as defined in claims 44-46, to enable one of ordinary skill to obtain the concept of the claimed subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees", an undertaking which is clearly prohibited by law. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989).

Accordingly, claims 44-46 are believed to be allowable, for the reasons expressed above, and consistent with claims 3, 9, 12, and 18 which have already been indicated to be allowable in the Office Action

3. CONCLUSION AND AUTHORIZATION OF DEPOSIT ACCOUNT

In view of the foregoing, applicants believe that claims 1-46 are all allowable and the same is respectfully requested. If any impediment to the allowance of these claims remains after entry of this Amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to initiate the same.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 50-0836.

DATED this 21 day of October, 2003.

Respectfully submitted,

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